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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,368	07/29/2003	Luiz Belardinelli	02-479-C	6263

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EXAMINER
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,368	BELARDINELLI, LUIZ	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 3, 2007 (amdt)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-15, 17-18 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims **5, 16 and 19-20** were previously cancelled, claims **1, 6-9 and 17** have been amended, the disclosure has not been further amended, and no new claims have been added as per the amendment filed October 3, 2007. No supplemental or additional Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1-4, 6-15, 17-18 and 21-30** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims *1-11* of copending Application No. **11/253,322** (now cited as a PG PUBS document; see PTO-1449 ref. **B6**).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of imaging and the alleged active ingredient (CVT-3146) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant has noted the above rejection but has argued that the above rejection is inappropriate because certain limitations found in the instant claims are, in applicant's view, distinguishing over the prior art. Applicant appears to be applying the standard of -- 101 double patenting --, as opposed to the above stated "obviousness-type double patenting," a major difference and a difference that requires examiner to point out that the cited application in its PGPubs document (**'625**) at page 1, column 2, paragraph **0011** that blood flow can increase within the range of 16.5 cm/sec to about 77 cm/sec., and at paragraph **0012** discloses that CVT-3146 ("regadenoson") can be administered in dosages ranging from "about 10 to about 500 micrograms." The former flow increase can not be reduced to a "fold increase in flow" number based on data supplied in the "**625** specification (no normal flow data could be located), but the latter dosage range clearly overlaps with what applicant has claimed herein ("10 to about 600 micrograms"). Therefore, in view of the latter overlap alone, examiner has determined that maintenance of the instant ground of rejection is necessary and appropriate.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***21-61*** of copending Application No. **10/766,403** (now cited as a PG PUBS document; see PTO-1449 ref. **A6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the PGPubs document **'915** corresponding to the instant application at paragraphs **0031** and **0045**, wherein both the flow multiple of 2.5 and the overlapping of dosages with the instant claims both render the finding of obviousness-type double patenting fully justified. This view of further confirmed by claims ***34 and 54-55*** of the noted **'915** document wherein both noted overlaps have been repeated. For these reason the rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***11, 14-27, 29-30, 34 and 36-37*** of copending Application No. **11/070,768** (now cited as a PG PUBS document; see PTO-1449 ref. **E6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the PGPubs document **'535** corresponding to the instant application at paragraphs **0010, 0058, 0094** and **0102**, wherein both the flow multiple of greater than 2.5 and the overlapping of dosages with the instant claims both render the finding of obviousness-type double patenting fully justified. For these reason the rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***5-8 and 10-22*** of U. S. Patent **7,183,264** (See PG Pubs ref. US 2004/0038928; PTO-1449 (#6) ref. **D6**; see also PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve

administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the **'264** patent at column 15, lines 8-12, and at column 31, lines 55-65, and to claims ***10, 11, 14-18 and 21-22*** wherein the dosage is specified as being in the range of 0.01 to 100 milligrams/kg (aka 10 micrograms to 100,000 micrograms/kg), or wherein the dosage is "sufficient" to cause selective vasodilatation (aka coronary blood vessel dilation) adequate for imaging coronary activity in a mammal, and wherein the increase in blood flow is greater than 2.5 of normal flow (see data at column 31, Table 6). The above limitations in the disclosure and the claims of the **'264** patent provide sufficient grounds to maintain the above rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***10-24*** of U. S. Patent No. **7,144,872** (PTO-1449 (#6) ref. **AA6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred the **'872** patent at column 125, lines 6-10, to column 32, lines 20-30, and to column 34, claims ***10, 12, 13, 16 and 19-20*** wherein the particular limitations noted in applicant's arguments are obvious variants overlapping with the limitations in the instant claims. For these reasons the instant rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***9, 10 and 16*** of U. S.

Patent No. **6,641,210** (PTO-1449 (#6) ref. **H6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to column 342, lines 15-30, and to columns 35-36, wherein the increase in coronary blood flow of greater than 2.5 fold and following administration of "sufficient" CVT-3146 (aka compound 16 or CVT-510) to induce a "coronary steal situation for the purposes of imaging the heart" by "dilating the coronary blood vessels" have been disclosed and/or claimed. Therefore, the above rejection remains appropriate and has been repeated herein.

Claims **11, 14-17, 24-27, 29-30, 34 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***11-13*** of U. S. Patent No. **6,403,567** (PTO-1449 (#1) ref. **AB1**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the '**567** patent at column 20, claims ***11 and 12*** which are directed to subject matter clearly overlapping with the subject matter claimed herein. Therefore, the above rejection remains valid and has been repeated herein.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4*** of U. S. Application No. **11/588,834** (PTO-1449 (#6) ref. **G6**). Although the conflicting claims are not identical,

they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033 . Therefore the two applications are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the PGPubs equivalent to this application (US 2007/0203090 A1) at page 18, column 1, paragraph **0153** and to pages 18-19 and claims ***26, 27-30, 33 and 37-38*** wherein the subject matter therein overlaps with the subject matter claimed herein. Therefore, the instant ground of rejection is found to remain valid and therefore has been repeated herein.

Claims **1-5, 6-15, 17-18 and 21-30** of this application conflict with the noted claims of U. S Patent Application Numbers **11/253,322, 10/766,403, 11/070,768 and 11/588,834**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

The prior art rejections of the previous Office action have been withdrawn in view of the presence above of a double patenting rejection, and of what appears to have been an incomplete reduction to practice in the **Gao et al.** reference wherein at the end of the Abstract and in the concluding paragraphs, the possibility that CVT-3146 might be useful for the instant claimed process was speculated upon, but the details of how this might be, or had been, executed were not provided.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about

the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

/L. E. C./

Patent Examiner, Art Unit 1623

LECrane:lec
06/05/2008

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